REMARKS

In the Office Action, claims 1, 6 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Nutter *et al.* (WO 98/11883) in view of Todd *et al.* (U.S. Patent 5,082,975), and claims 3-5, 12, 14, 15, 17-21, 23 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Nutter *et al.* in view of Todd *et al.* and Lefren *et al.* (U.S. Patent No. 4,431,427). Claims 8 and 22 were objected to as being dependent upon a rejected claim but would be allowable if rewritten.

35 U.S.C. § 103(a)

Independent claims 1, 12, 15 and 23 have been amended to recite that the compound kills, inhibits, or otherwise controls the growth or proliferation of S. aureus without preventing the growth of Lactobacillus at a pH in the range of 4.5 to 5.0. This amendment has a basis at page 7, lines 17-18 of the specification. It is believed that this limitation distinguishes amended independent claims 1, 12, 15 and 23 from the prior art.

In particular, the last four lines of page 6 of the Office Action note that the data in Table 1 of the specification and the Declaration of the inventor filed November 25, 2003 indicate the inhibitory action of hop acids against bacteria is pH dependent and that this limitation was not indicated in the claims. Accordingly, the pH limitation discussed above has been added to the amended claims.

Nutter *et al.* was cited as teaching the inhibition of the bacterial growth of S. aureus using hexahydrocolupulone (HHC). It was acknowledged in the Office Action that Nutter *et al.* do not indicate that HHC at 0.2-25 ppm would not prevent growth of Lactobacilli. Todd *et al.* was cited as teaching that HHC at high concentrations inhibits

the growth of Lactobacilli. The Office Action suggests that Todd *et al.* teaches that the administration of HHC at a concentration of between 0.2 and 25 ppm will lessen the inhibition of lactobacilli, thus allowing lactobacillus to grow. However, this assertion is not supported by Todd *et al.* as the reference does not state anywhere that HHC concentration levels below 50 ppm will lessen the inhibitory effect of HHC on lactobacilli, and hindsight created by the present application should not be used to support such a conclusion.

The Todd *et al.* reference should be reviewed for what it teaches, and it teaches only that lactobacillus may be killed at concentration levels above 50 ppm. The problem is that Todd *et al.* does not report any experiments being conducted at concentrations below 50 ppm and therefore provides no guidance whatsoever as to whether and at what concentrations below 50 ppm HHC will stop inhibiting lactobacilli growth and proliferation. In the absence of any evidence to the contrary, one of ordinary skill in the art could readily believe that concentrations as low as 0.2 ppm could also be effective in preventing the growth of lactobacillus.

As stated in the previous response, the Inventor's Declaration of November 25, 2003 makes it clear that without the benefit of the experiments reported in the present patent application, it would have been impossible to predict the effects of a lower concentration of HHC (such as in the range of 0.2-25 ppm) on the growth of lactobacilli. It was further noted that even though Todd *et al.* show that hexahydrocolupulone inhibits the growth of certain lactobacilli in milk (pH 6.4-6.8) at 50-200 ppm, these experiments cannot be used to predict lactobacilli anti-bacterial action at the vaginal pH of 4.5-5.0 as recited in the amended independent claims. Thus, the activity of hop acids

on lactobacilli below the 50 ppm level reported in Todd *et al.* at vaginal pH of 4.5-5.0 as recited in the amended claims could not be predicted from Todd *et al.*

Conclusion

The Applicants respectfully submit that amended claims independent claims 1, 12, 15 and 23 (and claims 3-8, 14, 17-22 and 25 that depend thereon) are in condition for allowance. Favorable reconsideration is respectfully requested.

No fees are believed to be needed for this amendment. However, if additional fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

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By: _____

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